REMARKS

The Office Action

Claims 1-5 are pending in this application. Claims 1-2 are withdrawn and claims 3-5 were examined.

Claims 4-5 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Claims 3-5 stand rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. Claims 3-5 stand further rejected under 35 U.S.C. § 103 as obvious over Janusz et al. (U.S. Patent Application No. 2005/0152985; "Janusz") in view of De Vita et al. (Cancer Principles & Practice of Oncology, 6th ed., Lippincott Williams & Wilkins, Philadelphia, 2001, pp. 308-312; "De Vita").

Status of Claims

This paper amends claims 3-4, cancels claim 5, and adds claims 6-24. Following the present amendment, claims 3-4 and 6-24 are pending and under examination.

Support for Amendments

Support for the amendment to claim 3 is found generally throughout the specification and specifically, for example, at page 1, lines 30-31 where Applicant specifically identifies one anti-tumor substance as an antibody.

Support for the amendments to claim 4 and for new claims 6-24 are found generally throughout the specification and in the claims as originally filed.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 4-5 stand rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Specifically, the Examiner asserts that the specification does not provide reasonable enablement commensurate in scope with the claims for isolating an anti-tumor substance from the colostrum of even-toe hoofed animals.

Applicant respectfully directs the Examiner's attention to the amendment to claim 3 made herein. Specifically, Applicant limits the claims to a method for isolating an antibody having anti-tumor properties from the colostrum. Support for this amendment is found in the

specification at page 1, lines 30-31. Thus, in addition to the specific examples of isolation methods provided in the specification, the skilled artisan immediately appreciates a plethora of methods for recovering the immunoglobulin fraction from colostrum. The amount of experimentation that is required to recover antibodies from colostrum is nothing more than routine.

Accordingly and in view of the current amendment, this rejection has been traversed and should now be withdrawn. Such action is respectfully requested.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 3-5 stand rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. The Examiner asserts that the claims are generally narrative and indefinite, and fail to conform with current U.S. practice. Applicant directs the Examiner's attention to the amendments made herein and submits that the claims, as currently presented, are not indefinite. Accordingly, this rejection may be withdrawn and such action is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 3-5 stand rejected under 35 U.S.C. § 103 as obvious over Janusz et al. (U.S. Patent Application No. 2005/0152985; "Janusz") in view of De Vita et al. (Cancer Principles & Practice of Oncology, 6th ed., Lippincott Williams & Wilkins, Philadelphia, 2001, pp. 308-312; "De Vita"). Specifically, the Examiner asserts that Janusz teaches that mammalian colostrum contains the polypeptide colostrinin which, *inter alia*, stimulates cytokine release from lymphocytes. De Vita teaches that particular cytokines have anti-cancer properties. The Examiner notes that Janusz does not disclose using colostrum from even-toe hoofed animals with leucosis as a starting material, but concludes nonetheless that the claimed invention is obvious. Applicant disagrees.

Applicant first points out that the claims as currently amended require that the anti-tumor substance isolated from the colostrum is an antibody. Colostrinin is not an antibody. For this reason alone, the rejection is traversed and should be withdrawn.

In applying this rejection, the Examiner incorrectly overlooks the requirement that the colostrum used in the claimed method be obtained from a mammal having leucosis. The

leucosis-positive status of the source mammal is a significant claim limitation for which the Examiner has identified no direct teaching or suggestion in the prior art. Further, the leucosis status of the source animal is scientifically significant to the claimed invention.

Applicant has recognized that even-toe hoofed mammals have increased resistance against leucosis compared to humans and, despite the disease, usually remain clinically normal. See, for example, Specification at p. 1, ll. 12-16 and WO 02/07739. It is believed that this increased resistance is the result of the production of anti-leucosis antibodies in diseased mammals. Applicant has discovered that these antibodies are present in the colostrum of diseased mammals at higher levels compared to their healthy counterparts—if the antibodies are present in healthy colostrum at all. The presently claimed method recognizes these differences and requires the use of colostrum from diseased mammals.

Applicant further demonstrates that a substance isolated from diseased colostrum using the claimed method is therapeutically beneficial when orally administered to test subjects. Specification at p. 3, ll. 12-21. Healthy colostrum subjected to the same separation method had a reduced therapeutic effect, or no effect at all, compared to the leucosis colostrum.

Thus, it is inappropriate to equate the colostrum of healthy animals with that of animals having leucosis for the purposes of the presently claimed method. Accordingly, this rejection should be withdrawn and such action is respectfully requested.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested. If the Examiner should have any questions concerning this communication or feels that an interview would be helpful to expedite allowance of this case, the Examiner is requested to call Applicant's undersigned attorney.

Respectfully submitted,

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